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CIS Congressional Information Service Washington D.C.

101st Congress
2d Session

COMMITTEE PRINT

S. PRT.
101-69

SKYROCKETING PRESCRIPTION DRUG PRICES: TURNING A BAD DEAL INTO A FAIR DEAL

A MAJORITY STAFF REPORT

OF THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

JANUARY 1990

Serial No. 101-F

This document has been printed for information purposes. It does not offer findings or recommendations by this committee.

U.S. GOVERNMENT PRINTING OFFICE

25-628 WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
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FOREWORD

There can be little doubt that we face a growing crisis in the United States due to rising prescription drug prices. Just prior to adjournment Congress took unprecedented action to repeal Medicare's new prescription drug benefit, primarily due to rising drug prices. We took this action at a time when drug costs represent the highest out-of-pocket health care cost for three out of every four older Americans.

But it isn't just the eldest Americans who are suffering. State Medicaid programs that serve the poorest Americans have struggled through this decade -- by chopping and chiseling at their drug coverage. The States have raised copayments, cut benefits, imposed coverage restrictions, and held down pharmacy reimbursement. In fact, they've done everything but get manufacturers to stop raising their prices at a rate three times faster than inflation. As a result, Medicaid drug spending is now over $3.3 billion a year -- even more than we spend on doctors in that program.

And it isn't just the poorest Americans who are suffering, nor is it just a problem for government programs. Ordinary citizens are going to extraordinary lengths to find less expensive drug treatment. Some find they must spend their life savings on prescription drugs. People with AIDS have been pushed into buying life-sustaining drugs from foreign countries. And now one of the companies that set the price so high wants the U.S. Government to seize these low-cost drugs at the border!

Why should anyone have to risk arrest to find a reasonably priced prescription drug? It is our responsibility to find a way to get drug costs down to a reasonable level. After the Committee's July hearing on prescription drug prices, I assigned Committee staff to look at what it is that foreign governments are doing to keep drug costs low, and to discover what the most innovative people in the private sector are doing to keep drug costs low. This second Committee staff report chronicles the findings of that staff study, and makes recommendations for action by the U.S. Congress.

As a result of the Committee's July and November 1989 hearings and accompanying staff reports, I believe Government -- particularly the State Medicaid programs that insure the poorest Americans -- can and should be bargaining with drug makers over the price of their drug products. Accordingly, I intend to introduce legislation early this year to help States control spiraling drug costs by negotiating prices with manufacturers.

David Pryor
Chairman, United States Senate
Special Committee on Aging

United States Senate
Special Committee on Aging
David Pryor, Chairman

Majority Staff Report

SKYROCKETING PRESCRIPTION DRUG PRICES: TURNING A BAD DEAL INTO A FAIR DEAL

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UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING

MAJORITY STAFF REPORT

SKYROCKETING PRESCRIPTION DRUG PRICES:

TURNING A BAD DEAL INTO A FAIR DEAL

INTRODUCTION

Federal and State governments have traditionally subordinated the prudent purchasing of prescription drugs to the goal of providing manufacturers with financial incentives to create new drug products. Unfortunately, despite a massive and ongoing public investment in prescription drug research and development, most new drugs introduced into the U.S. market in this decade have been assessed by the Food and Drug Administration as essentially duplicating already available products.

Contrary to sound business principles, Federal and State Governments have continued to reward manufacturers' poverty of innovation by paying premium prices, even for duplicative drug products. In fact, as prescription drug price increases have outpaced inflation by more than threefold during the last decade, policymakers have done little to directly address increased prescription drug prices, but have instead cut back reimbursement to pharmacists and have limited or eliminated essential health benefits for needy Americans.

As a result of their failure to take action, despite their enormous purchasing power, Federal and State governments -- as evidenced by the Medicaid program -- continue to pay higher prices for prescription drugs than any other large buyer in the marketplace. This report is intended to facilitate action by Congress and by States to control rapidly escalating drug prices that now threaten access to comprehensive health care services.

In contrast with governmental programs, the private sector has responded to rapid price increases by instituting practical and successful economic incentives for drug manufacturers to lower their prices. The Chairman of the Aging Committee assigned staff to determine whether government could learn from the private sector and adopt a more businesslike approach to the procurement of prescription drug products for American citizens.

In addition, the Chairman directed staff to gather information on strategies employed by foreign governments attempting to control drug prices while promoting significant innovation and broad public access to the fruits of progress. Several international comparisons of drug prices were reviewed, including documents describing the widely varying reimbursement and price control schemes present in member countries of the European Economic Community (EEC).

Because none of the existing international pricing studies were entirely satisfactory, staff worked over a period of several months with economists at the Belgian Consumer Association to prepare an international drug price comparison, based on a methodology employed for a major study published by the Bureau of European Consumers Unions (BEUC). The analysis performed for the Committee is based upon 1988 prices for 25 identical brand name prescription drug products which are commonly sold in the United States and EEC nations. International prescription drug consumption rates were also analyzed, to place in proper context the impact of drug price discrepancies on consumers living in these countries.

In addition to the experts and materials described above, numerous reports by and discussions with representatives of drug manufacturers, consultants, and other health care professionals contributed to the analysis presented below.

BACKGROUND AND METHODOLOGY

The Committee's previous staff report (Committee Print No. 101-D, August 1989) analyzed pricing data and Food and Drug Administration (FDA) evaluations of new drugs, finding that high prescription drug prices are poorly correlated with innovation. High priced "me-too" drugs flooded the U.S. market during the 1980s but added little or no value to existing therapies. The Committee's August staff report concluded with the following questions to guide further research into the problem of prescription drug prices:

- How can government at all levels facilitate meaningful innovation by pharmaceutical manufacturers?
- How can the Medicaid and Medicare programs achieve the efficiencies in purchasing pharmaceuticals already realized by the Department of Veterans' Affairs?
- What, if anything, are foreign governments doing to hold down pharmaceutical prices for their citizenries?
- Why will some manufacturers negotiate drug prices with some or all buyers, while others maintain a "policy" of not bidding in response to solicitations?

This follow-up report addresses these questions, focusing on the potential for significant savings in the $3.3 billion Medicaid prescription drug program. This report also updates and expands the Committee's examination of the contention that high drug prices are necessitated by the high cost of research and development needed to create breakthrough medical therapies.

As a first step, staff sought to learn whether economies, achieved as a result of unusually low research and development costs for certain drugs, have been passed on to the consumer in the form of lower prices. To study this question, staff examined price histories for products with research and development costs that were known to be much lower than the industry average. Research and development costs associated with the examples given in the report were lower for a variety of reasons, including discovery and marketing of the drug many years prior to U.S. marketing, and substantial governmental funding of basic research.

The second objective of this staff study is to identify business practices by which prudent buyers in the U.S. market secure reasonable drug prices. This was done to ascertain the feasibility of extending some of these practices to governmental programs. Staff conducted a telephone survey of pharmacy directors employed by: 63 U.S. hospitals (from a randomly selected national sample of 75), 50 State Medicaid programs, 12 major health maintenance organizations (HMOs), and 4 large hospital/nursing home prescription drug buying groups (see Appendix A for a summary of results).

EXECUTIVE SUMMARY

Finding 1: Skyrocketing prescription drug costs have collided with funding limitations in Medicaid, the taxpayer funded health care program for the poorest Americans, resulting in cutbacks that impede access to prescription drugs and other essential health care items and services.

Finding 2: There is evidence that prescription drug manufacturers price their products as high "as the market will bear," rather than setting prices based on the amount of revenue needed to recoup the cost of their investment in research and development.

Finding 3: Physicians and pharmacists in over 90% of the nation's hospitals and at least 42% of U.S. health maintenance organizations (HMOs) have independently concluded that many prescription drugs are therapeutically interchangeable when used to treat patients suffering from the same ailment.

Finding 4: Based on the knowledge that many different drug products are often used to treat the same medical condition, hundreds of hospitals and HMOs have forced drug manufacturers to compete and offer reduced prices in order to be listed as a preferred product on the hospital or HMO formulary.

Finding 5: With the growing success of negotiated drug prices by HMOs and hospitals, manufacturers have increasingly devoted their sales forces to lobby, curry favor with, and even intimidate formulary managers into purchasing their products.

Finding 6: Prescription drug manufacturers have waged an all-out national campaign to undermine and frustrate State efforts to negotiate lower prices for therapeutically duplicative drugs.

Finding 7: Medicaid programs typically do not use their formulary process to negotiate drug prices with manufacturers, are much more open to manufacturer influence, and pay much higher prices than hospitals and HMOs for the same drug products.

Finding 8: Medicaid prescription drug programs can save millions of dollars by creating therapeutic formularies, if the formulary is based upon clinically well-founded comparisons of safety, efficacy, and cost, and is used in price negotiations with manufacturers.

Finding 9: Taking into account the impact of high prices and high prescription drug consumption in the United States, Americans not only spend more for prescription drugs than the citizens of any nation in the European Economic Community (EEC), but are also less well protected by health insurance, contributing to the competitive disadvantage of U.S. employers in the international economy.

FINDINGS

Finding 1: Skyrocketing prescription drug costs have collided with funding limitations in Medicaid, the taxpayer funded health care program for the poorest Americans, resulting in cutbacks that impede access to prescription drugs and other essential health care items and services.

- From 1984-87, while expenditures for Medicaid have increased faster than any other component of State budgets (except Corrections), prescription drug expenditures outpaced Medicaid spending for all acute and long term care services but home health and facilities for the mentally retarded, according to a July 1989 report by the Urban Institute.

- By 1988, Medicaid paid $3.3 billion for prescription drugs, more than for physician payments, making it the fourth highest category of Medicaid spending.

- Many States have responded to burgeoning drug program costs by imposing arbitrary monthly or annual limitations on the number and/or reimbursable cost of prescriptions each beneficiary may purchase, by raising copayment obligations and by reducing real reimbursement for pharmacy services.

  Committee staff reviewed State Medicaid program changes reported to the Intergovernmental Health Policy Project between 1981 and 1988, finding that 18 States adopted more restrictive policies in these areas, while only 7 States loosened restrictions.

  Nine States either adopted or modified drug formularies during this period, often removing entire classes of drugs (e.g., anti-anemia, anti-anxiety, or the anti-ulcer drugs known as "H2 antagonists") from coverage.

Finding 2: There is evidence that prescription drug manufacturers price their products as high "as the market will bear," rather than setting prices based on the amount of revenue needed to recoup the cost of their investment in research and development.

- Mestinon (Pyridostigmine Bromide), a prescription drug used to treat the nervous system disease Myasthenia Gravis, has been on the U.S. market for many years and is off-patent. The published average wholesale price (AWP) for a month's supply has risen by over 266% since April 1980. 80% of persons with Myasthenia Gravis are totally dependent upon the drug to stay alive and healthy, and there is no generic product available.

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In 1989, shortly after purchasing the marketing rights to Mestinon from Hoffmann-La Roche, ICN Pharmaceuticals refused to renew special low price contracts with Myasthenia Gravis "pill banks" -- raising the price from about $30/100 pills to over $80 overnight for thousands of patients. ICN has informed the Myasthenia Gravis Foundation of its intention to raise the price of Mestinon by at least another 8% effective December 1, 1989.

- Eldepryl (Selegiline HCl), a prescription drug most often used along with Levodopa to treat Parkinson's disease (and recently reported to be of use as a therapy initiated before levodopa treatment), was invented in Budapest, Hungary in 1964. It has been widely used in Europe as an adjunct to Levodopa therapy since the early 1980s (known as Jumex in Hungary and Austria, Jumexal in Switzerland, and Movergan in Germany).

  In 1989, Somerset Labs received approval to market Eldepryl in the United States. Because the population of users is expected to be well under 200,000 persons, the Food and Drug Administration granted "orphan drug" status to Eldepryl. This means the company gets tax credits and exclusive rights to market the drug in the United States for 7 years.

  An unknown number of U.S. citizens have been obtaining this drug by mail from overseas for several years, but may be subject to having their imported Eldepryl seized by Customs agents at the U.S. border, now that the drug is approved for use in the United States.

  Eldepryl was available in the Summer of 1989 at a retail cost of 41-46 cents/pill in Rome, Italy, 79 cents/pill in Vienna, Austria, and for $1-$1.12/pill in Toronto, Canada -- but the American Parkinson's patient must pay $2 per pill, or $730/year (typically taken twice daily).

- NebuPent (aerosolized Pentamidine) is a prescription drug used for treatment and prevention of <u>pneumocystis carinii</u> pneumonia (PCP), a virulent pneumonia responsible for the death of about three-quarters of the people infected with the AIDS virus. The drug was discovered and used to treat sleeping sickness in 1945. In 1958, Hungarian researchers found it effective in treating PCP. European supplies were used for many years in the United States, but due to the AIDS crisis, by 1984 supplies were running short and the U.S. Government invited some American firms to make the drug. Lyphomed, Inc. responded and was awarded "orphan drug" status for its intravenous (IV) Pentamidine in 1984.

By 1987, with grant support from the National Institutes of Health, researchers at Sloan Kettering Memorial Cancer Center and elsewhere determined that regular use of the aerosolized form of the drug would prevent the onset of PCP. Lyphomed and another firm, Fisons, sought to secure "orphan drug" status and marketing approval from the FDA. Lyphomed's product was approved first, and has exclusive rights to the U.S. market for 7 years.

The aerosolized form is made from a 300 mg dose identical to the IV dosage (with a different label), for the same price. Lyphomed has steadily raised the price of the IV form of Pentamidine since its 1984 approval -- from about $25/vial to the current wholesale price of about $99/vial (a vial is about 1 month's supply; retail prices are reportedly about $120/vial).

People infected with the AIDS virus have found the price very difficult to afford, due to their numerous other medical costs and their loss of workplace-based health insurance due to increasing disability. Many have been obtaining the drug by mail from pharmacies in England for about $25/vial (retail, including postage, $40). Lyphomed has stated that the product is marketed by an English manufacturer in Canada for about $60 (U.S.), and in Australia for about $80 (U.S.).

Lyphomed wrote to the Food and Drug Administration on October 5, 1989 and on November 17, 1989, requesting that any Pentamidine imported from abroad should be seized at the U.S. border. FDA has acknowledged Lyphomed's inquiry but has not yet stated whether it intends to comply with the firm's request.

Though importation of foreign unapproved drug products into the United States is illegal, current FDA policy encourages FDA field office personnel to "consider a more permissive policy" under certain circumstances, such as when a drug is being imported for personal use in quantities of less than three months' supply, the product is not known to represent an unreasonable risk, the product cannot be obtained by the patient in this country, and/or the patient affirms s/he is under the care of a physician in the United States who is responsible for his/her care.

Finding 3: Physicians and pharmacists in over 90% of the nation's hospitals and at least 42% of U.S. health maintenance organizations (HMOs) have independently concluded that many prescription drugs are therapeutically interchangeable when used to treat patients suffering from the same ailment.

- This consensus among expert members of hospital and HMO pharmacy and therapeutics committees is consistent with FDA's judgment that the overwhelming majority of new drugs, though chemically different, simply duplicate the therapeutic attributes of drugs already on the market.

- Surveyed health care institutions generally agreed that many interchangeable drug products exist in the following therapeutic categories:

  Anti-ulcer drugs called "H2 antagonists";

  Anti-arthritis pain drugs called "Non-Steroidal Anti-Inflammatory Drugs" (NSAIDs);

  Antibiotic drugs known as "Cephalosporins";

  Other frequently mentioned drug categories with several interchangeable products included topical steroids; antihistamines; antacids; potassium supplements; and vitamin preparations.

Finding 4: Based on the knowledge that many different drug products are often used to treat the same medical condition, hundreds of hospitals and HMOs have forced drug manufacturers to compete and offer reduced prices in order to be listed as a preferred product on the hospital or HMO formulary.

- Using a formulary allows a health care provider to channel most or nearly all of its drug purchases for a given therapy (e.g. peptic ulcer treatment) to just one or two of the many manufacturers of therapeutically duplicative drug products. Manufacturers can and do offer substantial discounts (25% or more) in exchange for the increased sales volume that results from having their product (and not their competitors') listed in the formulary.

- Even large hospital buying groups, which are already able to obtain low drug prices from manufacturers without using formularies, are exploring ways of implementing multi-hospital formularies to further improve their negotiating posture.

  One large buying group representing 220 member hospitals successfully negotiated an agreement to purchase just one of the four high-priced anti-ulcer drugs called "H2 antagonists" -- for an estimated savings of $25 million over the 4 year life of the contract.

- Community pharmacies have so far generally been unable to benefit from the financial advantages of formularies, largely due to their need to stock a wide variety of products that individual physicians prescribe.

Finding 5: With the growing success of negotiated drug prices by HMOs and hospitals, manufacturers have increasingly devoted their sales forces to lobby, curry favor with, and even intimidate formulary managers into purchasing their products.

- One manufacturer threatened to sue an HMO whose educational newsletter simply informed physicians that the manufacturer's anti-arthritis drug was a "me-too" drug, offering no therapeutic advantages over less-expensive products. When the HMO stood by its clinical assessment of the "me-too" drug product, the manufacturer dropped its threat to sue, and sought instead to convince the HMO to republish a revised article at the manufacturer's expense (the HMO refused).

- One pharmaceutical manufacturer's sales manager reportedly stated, "I can get any drug on a university hospital formulary. I just find some fertile soil -- the right person who is hungry for research money. It doesn't matter what the side effects are or if it's four times the price of an equally good drug; I know the researcher will help me get it on the formulary in exchange for research money." [Source: New York Times Magazine, November 5, 1989.]

- In the spring of 1989, the typical HMO pharmacy director reported an average of 3.4 sales calls by manufacturers per week, an increase of 16% over the fall 1988 survey period, according to Scott-Levin, a healthcare marketing information and consulting firm.

- Many manufacturers have reportedly sought to curry favor with HMOs, in particular, by giving them cash grants to conduct "educational seminars".

Finding 6: Prescription drug manufacturers have waged an all-out national campaign to undermine and frustrate State efforts to negotiate lower prices for therapeutically duplicative drugs.

- Drug companies, using arguments judged as lacking credibility by thousands of practicing clinicians in pharmacy and therapeutics committees across the nation, have succeeded in the political arena with their assertion that all prescription drug products are uniquely effective and distinct.

- Opposition from drug manufacturers has succeeded in blocking 13 out of 15 States' previous attempts to negotiate lower drug prices for their financially strapped Medicaid programs. (See Appendix B for a status of State negotiating arrangements.) A response by one Medicaid State that had a bid program describes the reason why they were unable to continue:

  "...Manufacturers just started dropping [their contracts] and soon there were none participating. Manufacturers said: 'We won't do this.'"

- Two California State legislators, a Democrat and a Republican, wrote to the Chairman on November 14, 1989 to describe their experience in trying to enact a program of direct negotiations between MediCal (California's Medicaid program) and drug manufacturers:

  "Assemblyman Bill Baker (R-Danville) introduced AB 2148 earlier this year to authorize the State of California to negotiate rebates from manufacturers of single source [patented] drugs...Incredibly, the drug manufacturers' main argument against AB 2148 went like this: One, they said, such a precedent in California could spread to other State Medicaid programs, Medicare, and other insurance type health programs.

  "Two, widespread use of such rebates would have a major impact on drug pricing. Therefore, the drug manufacturers said, they would not agree to pay rebates in order to keep a drug on the MediCal formulary...our bill failed in its first committee...[u]nder heavy pressure from the drug companies."

  If this program were to be implemented, State officials have estimated potential savings of $40 million to MediCal.

- Three additional State Medicaid programs (AL, GA, and KS) now have active drug price negotiation programs underway, but have been severely hampered by manufacturers' intensive lobbying and nearly uniform refusal to bid on State solicitations.

Finding 7: Medicaid programs typically do not use their formulary process to negotiate drug prices with manufacturers, are much more open to manufacturer influence, and pay much higher prices than hospitals and HMOs for the same drug products. (See Appendix A in this report and Appendix I in the Committee's August staff report.)

- 22 States reported that they currently maintain a drug formulary, but these vary a great deal in degree of restrictiveness. Two States (NJ and SD) will reimburse for virtually all FDA approved drug products. Of the States with formularies, the number of drug products included ranges from 1,200 to 45,000 (including non-prescription drugs), while the range of drug products on hospital and HMO formularies is from as few as 300 up to 20,000.

- Compared to HMO and hospital pharmacy and therapeutics (P&T) committees, Medicaid formulary committees tend to be more open to manufacturer influence, in that manufacturer representatives may directly suggest additions to the formulary, attend committee meetings, and may actually serve on the committee.

- In all Medicaid States, manufacturers typically initiate a request that a drug be covered or added to the formulary; whereas in hospitals and HMOs it must be a physician who initiates this request. In addition, formulary States do not always require a manufacturer to submit a formal application to initiate an addition request -- 7 of the 22 formulary States require only that a package of materials be sent to them by the manufacturer.

- While the primary function of Medicaid formulary committees is to approve or disapprove new drug products proposed for the formulary list, HMO and hospital P&T Committees have a much broader range of functions, such as improving the quality of prescribing and dispensing through adverse drug reaction and medication error reports, and drug utilization review (DUR).

- HMOs and hospitals expend more resources than States to educate physicians about formulary products, and to preclude unnecessary prescribing of expensive off-formulary products. Some of these educational efforts include articles in peer newsletters, educational symposia, one to one contact between pharmacist and physician, and distribution of a pocket-size formulary.

  The most sophisticated programs were in use at a handful of HMOs, which combined drug utilization review with physician education about the HMO's formulary.

Finding 8: Medicaid prescription drug programs can save millions of dollars by creating therapeutic formularies, if the formulary is based upon clinically well-founded comparisons of safety, efficacy, and cost, and is used in price negotiations with manufacturers.

- In addition to savings attributable to negotiated prices, discussed above, medical literature suggests formularies may improve patient care by identifying drugs of choice, for example by excluding those with more risky adverse effects, thereby saving both lives and money.

- Based upon the Committee staff's national survey of formularies presently in use in hospitals, HMOs, and Medicaid programs, the most successful formularies:

  Are founded on sound clinical judgments by a committee consisting of physicians, pharmacists, and other health professionals regarding therapeutic interchangeability;

  Ensure the availability of at least one (and sometimes several) high quality prescription drug product(s) for each therapeutic class of drugs;

  Ensure physicians may readily obtain an off-formulary drug for a patient with unusual needs (e.g. allergies to the listed drug or improved response from an off-formulary drug); and

Are not finalized (with respect to which products are to be listed), until manufacturers of all products identified as equally safe and effective have been given a chance to offer a lower price for their product.

- Many formularies, including some in use by State Medicaid programs, have a poor clinical basis and exclude entire categories of prescription drugs, or fail to cover true breakthrough drug products. These formularies may compromise the quality of patient care and raise health care costs by denying timely and appropriate prescription drug therapy to the poor.

Finding 9: Taking into account the impact of high prices and high prescription drug consumption in the United States, Americans not only spend more for prescription drugs than the citizens of any nation in the European Economic Community (EEC), but are also less well protected by health insurance, contributing to the competitive disadvantage of U.S. employers in the international economy.

- Average drug prices paid by American consumers are 54% higher than the average for all EEC nations, and are higher than drug prices even in the EEC nations with "free markets" for prescription drug prices (see Appendixes C and D).

  These data provided by the Belgian Consumer Association confirm the relationship between U.S. and EEC prices found in a methodologically different analysis performed in 1988 by the Italian pharmaceutical manufacturers' association, Farmindustria.

- The impact of higher drug prices on the average U.S. consumer is exacerbated by the much higher consumption rate of prescription drugs in the United States, compared to the nations of the EEC (see Appendix E).

  U.S. citizens are also more exposed than European citizens to the high cost of prescription drugs because there is no U.S. national health insurance for prescription drug costs. Thus, where drugs represent the highest out-of-pocket health care expense for 3 of every 4 older Americans, Europeans enjoy public insurance protection against drug costs, and pay an average of only 33% of their drug costs out of pocket (range: from 12% to 56%) (see Appendix F).

- The prescription drug market in the Federal Republic of Germany (FRG) has been one of those most free from government intervention historically. Citizens of the FRG pay among the highest prescription drug prices in Europe and also have high per capita consumption of prescription drugs, as do U.S. citizens.

  In response to the rising cost burden of prescription drugs, however, the FRG has recently taken steps to reduce both consumption rates and drug prices, to achieve cost savings in their national health insurance program.

- American employers have recently begun to consider ways to reduce rapidly escalating prescription drug outlays.

  General Motors estimates it will spend more than $300 million in 1989 for prescription drugs, over 20 percent more than in 1988.

  Rockwell International has reportedly received offers from manufacturers to cut drug prices, and is planning to open their own pharmacies to buy drugs in bulk at lower prices. In addition, Rockwell and four other companies have commissioned a study to examine the cost-effectiveness of contracting with pharmacies.

  Employers now reducing pharmacy costs may show incremental savings in the first year or two, but will likely find it necessary to achieve actual reductions in drug product cost. This is likely because pharmacy profit margins are thin, and because drug product costs account for about 70% of the cost of each prescription, while pharmacy costs account for a shrinking share of about 30% (see Appendixes K and L in the Committee's August staff report).

RECOMMENDED LEGISLATIVE OPTIONS

The data and analysis presented in this and the previous majority staff report formed the basis for three options for legislation to directly address problems raised in these two reports. In addition, several key policy goals guided the development of these options:

1. Ensure Medicaid beneficiaries have access to a full range of essential pharmaceutical items and services.

2. Ensure physicians retain the prerogative to prescribe any drug medically necessary for treatment of an individual in their care.

3. Assist physicians in identifying drugs of choice, based on objective scientific and clinical evaluations of relative safety, efficacy, and -- for drugs already judged to be equally safe and effective -- relative cost.

4. Provide State Medicaid programs with relief from the rapid escalation of prescription drug prices.

5. Focus cost containment efforts in Medicaid prescription drug programs on the source of cost increases -- manufacturer price setting for drug products -- rather than pharmacy costs.

6. Build new governmental price negotiating mechanisms on the foundation laid down by existing business relationships between prescription drug manufacturers, health care providers and third party payors.

Guided by these goals, Committee staff have developed three options to mitigate the impact of rising drug prices. The three options include (1) a voluntary approach designed to assist States in arriving at scientifically and clinically valid assessments of drug equivalency, (2) a "flexible mandate" that encourages immediate State action in anticipation of an eventual Federal mandate, and (3) a centralized, mandated Federal program. A mandate would be enforced through approval of State Medicaid plans by the Secretary of Health and Human Services (HHS).

Option 1: Voluntary Educational Program. Direct the HHS Secretary to establish a National Pharmacy and Therapeutics (P&T) Committee (or contract with an existing non-governmental entity), consisting of panels of medical and scientific professionals. The National P&T Committee would review on an ongoing basis what is known about prescription drugs approved for U.S. marketing (providing monthly updates to reflect new developments), with the aim of determining which drug products are equally safe and effective therapeutic alternatives for one or more medical indications. The National P&T Committee would produce a list of therapeutically equivalent alternatives that could then be employed by States, at their option, to negotiate drug prices with manufacturers. States would be required to establish a prospective and retrospective Drug Utilization Review (DUR) program.

Option 2: Flexible Mandate. Set a date by which States must either join with other States in one of several multi-State Medicaid buying groups, or join a buying group established by the HHS Secretary and made up of several States. The purpose of these groups would be to negotiate prices of single source drugs with manufacturers. After the deadline established by statute, these groups would be required to rely upon the judgments of the National P&T Committee (described in Option 1, above) as to which drug products are equally safe and effective and can therefore be put out for competitive price bidding. Each State would be required to establish a DUR program, as in Option 1, above.

Each State or buying group would seek bids from each manufacturer of a drug in group of equally safe and effective drug products. Each State or buying group would identify the manufacturer which had offered the best price, and list that manufacturer's product (and not the others) in their list of preferred drug products. States would pay pharmacies the standard published Average Wholesale Price (AWP), and would obtain from manufacturers a rebate, based upon the volume of each manufacturer's product dispensed to qualified beneficiaries and the difference between the negotiated price and the published AWP.

Grandfather Clause. States which have established their own successful single- or multi-State price negotiating entity prior to the statutory deadline could have their programs grandfathered, subject to fundamental rules to ensure beneficiary access to medically necessary drugs. Likely rules would:

- Ensure any FDA-approved drug product will be covered for Medicaid reimbursement, even if it does not appear on a Medicaid buying group's list of preferred drugs, provided the patient's physician handwrites on the prescription "[drug name] medically necessary".

- Ensure all medically accepted uses of FDA approved prescription drugs (as described in a frequently-updated authoritative compendium to be selected by the individual State or buying group) are covered for reimbursement, whether or not the use appears in approved product labeling.

- Ensure that States maintain an active educational program to help physicians and pharmacists know which drug products are judged by objective experts as the drugs of choice.

Option 3: Mandatory National Medicaid Buying Program. Same as Option 2, but require States to participate in a single national buying group that would negotiate drug prices with manufacturers on their behalf. A DUR program would be required in each State, as in Options 1 and 2, and the fundamental rules to assure access (described in Option 2) would apply as well.

Summary Analysis of State Medicaid, Hospital and HMO Inquiries

In October 1989, staff of the Senate Special Committee on Aging undertook a survey of State Medicaid agencies, hospitals, Health Maintenance Organizations (HMOs), and hospital buying groups to determine how these entities organized their purchasing of prescription drugs. Committee staff conducted informal discussions with the pharmacy director (or other person responsible for pharmacy/drug procurement operations) in 50 State Medicaid agencies, 63 U.S. hospitals (from a random national sample of 75 U.S. hospitals), 12 HMOs (representing approximately 13 million members, or 39% of the HMO members as of January 1989), and 4 hospital and nursing home prescription drug buying groups.

These discussions focused along two primary lines of inquiry: (1) how these entities developed their list of preferred (in some cases, reimbursable) drugs, particularly the extent that clinical and scientific resources were employed to make these judgments; and (2) if, and how, these entities used this process to support drug price negotiations with drug manufacturers.

The results of these discussions are highlighted and summarized in the chart on the following page. Please note that staff have refrained from providing a more detailed statistical analysis because this was a survey effort designed only to identify trends and models.

Discussions with the buying groups were less comprehensive than those with the Medicaid States, hospitals and HMOs. Thus, the results do not lend themselves to the format presented in the following chart. Therefore, observations of discussions with buying groups are outlined below:

- A total of four buying groups were contacted with memberships ranging from 300 to over 1,400 hospitals.
- Usually, drug products are chosen for negotiation by a committee within the buying group composed of pharmacy director representatives from the member hospitals.
- Buying group contracts are for periods of from 1 to 5 years. Longer term contracts will include provisions for price adjustments should a price increase or decrease by a predetermined amount.

- Price negotiation for drug products determined to be therapeutically equivalent occurs on a limited basis. In one instance, a buying group obtained a good price for one of the group of anti-ulcer products called "H2 antagonists" by convening a focus group of approximately six pharmacy directors from large hospitals. This group reviewed all the H2 antagonists and chose one as the drug of choice. The group then reached a consensus that if a large number of member hospitals would agree to use this one drug, a better deal could be obtained from the manufacturer. 220 of the member hospitals agreed to participate and the buying group negotiated a discount estimated to save these members over $25 million over 4 years. This group has plans to take a similar approach with other therapeutic categories such as Cephalosporins, a group of antibiotic products.

SUMMARY ANALYSIS OF STATE MEDICAID, HOSPITAL AND HMO INQUIRIES

Issue	Medicaid States	Hospitals	HMOs
1. Number of Entities Queried	50	63	12
2. Number of Entities w/ Formulary	22	63	10
3. Number of Drugs on Formulary	1,200-45,000	300-20,000	500-4,000
4. Number that Allow Therapeutic Substitution*	None; Do allow therapeutic verification*	23 (34%) do for limited number of products	None; Do allow therapeutic verification*
5. Formulary Educational Efforts	May provide formulary list to physicians	Newsletters; One-on-one w/pharmacist, physician; pocket-size formulary; educational programs; distribution of P&T meeting minutes.	

SUMMARY ANALYSIS OF STATE MEDICAID, HOSPITAL AND HMO INQUIRIES
Continued

Issue	Medicaid States	Hospitals	HMOs
6. Typical P&T Committee Structure	9 members: Physicians and Pharmacists	Varies from 3 to 20: Physicians from various disciplines, pharmacists, RNs, QA reps	12: Physicians, pharmacists, plan reps
7. P&T Mtgs Open or Closed to Pharmaceutical Industry	Open	Closed to other than medical staff or plan physicians	
8. Functions of P&T Committees	Add/delete drugs	ADRs, quality assurance, medication errors, DUR, add/delete drugs	Add/delete drugs, DUR, plan policy
9. Process for Formulary Additions	In 15 of 22 formulary States, manufacturer completes an application	Usually medical staff requests: by phone, letter, or form; Sometimes by pharmacist	
10. Availability of Off-formulary Drug	Yes, may involve a cumbersome prior authorization process	Yes, simply prescribes; may require a phone call, letter, or form	
11. Number Negotiating Prices with Manufacturers	Only 3 States (See Appendix B)	61, either alone or through a buying group	11

Key

ADR - Adverse Drug Reaction

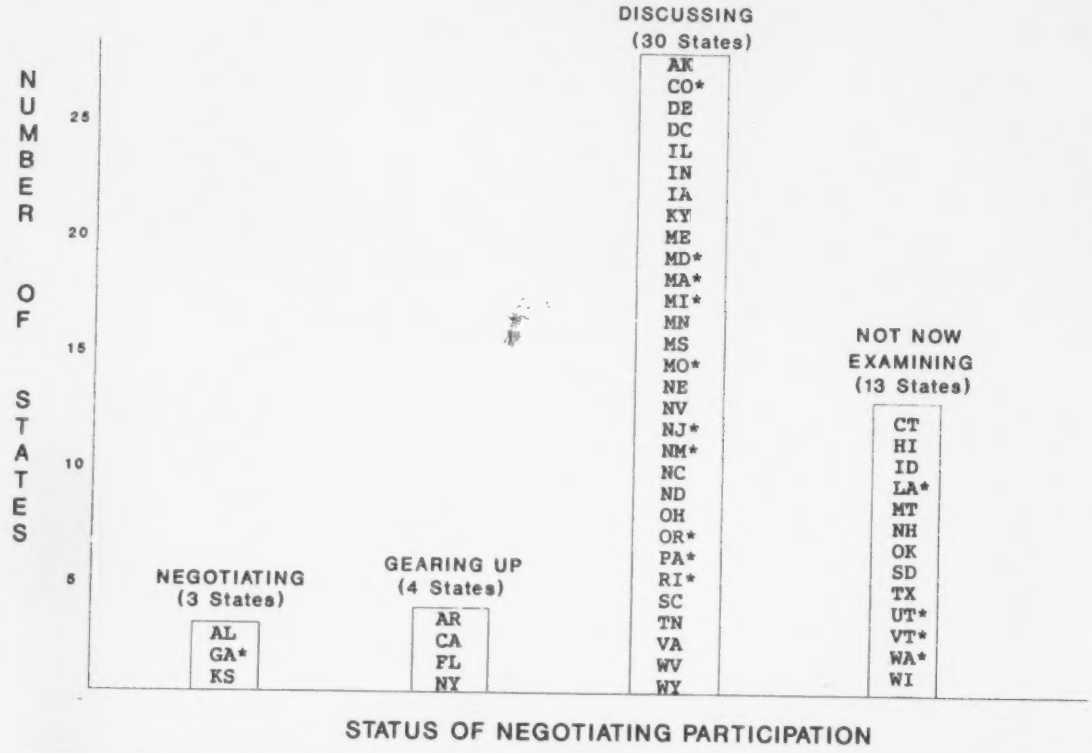
DUR - Drug Utilization Review

P&T - Pharmacy and Therapeutics Committee

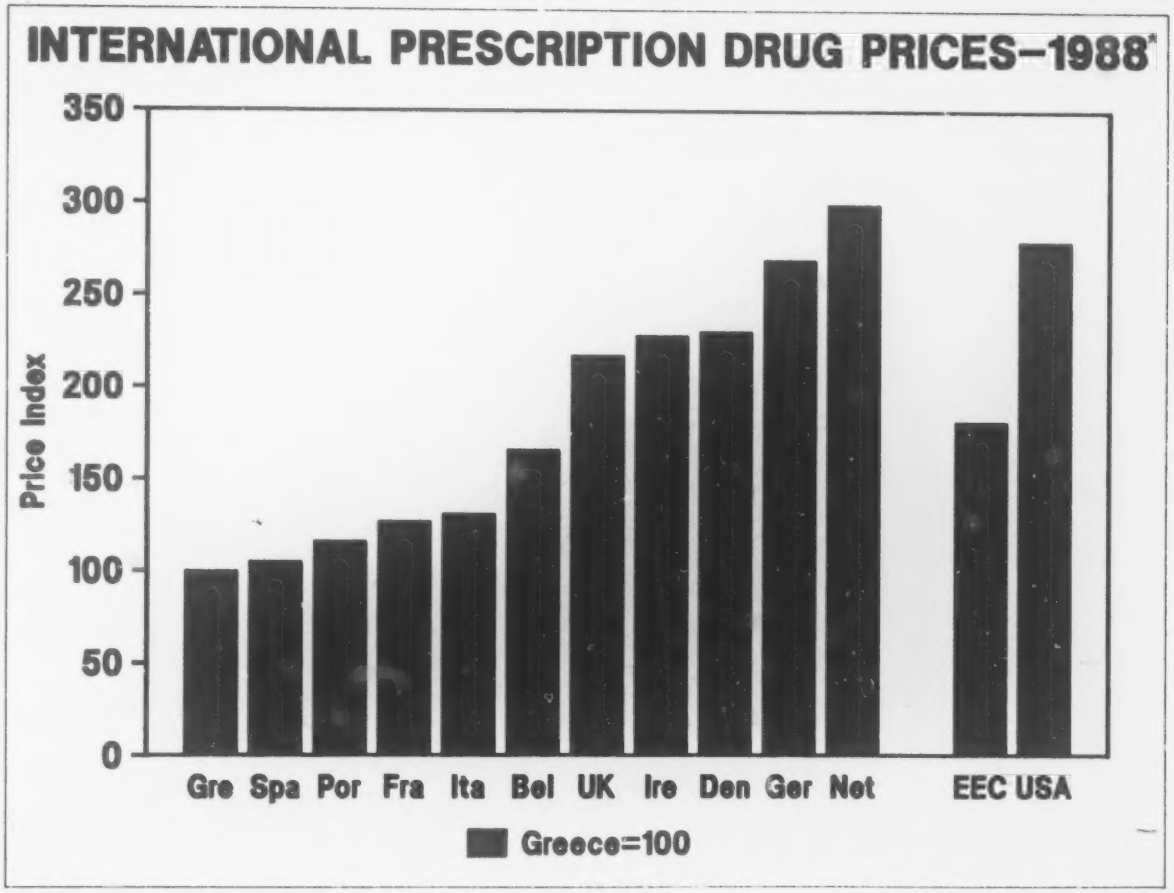
QA - Quality Assurance

* - See Appendix H, Definitions Used in This Report.

STATUS OF MEDICAID PROGRAMS' NEGOTIATING ARRANGEMENTS WITH DRUG MANUFACTURERS



SOURCE: Survey of 50 State Medicaid Programs, Senate Special Committee on Aging, October 1989.
* Indicates States that have attempted or succeeded in negotiating with drug manufacturers in the past.



* U.S. vs EEC drug prices of 25 identical drug products.

AVERAGE U.S. AND EEC PRICES OF LISTED PRODUCTS USED IN THE COMPARISON AND LOWEST AND HIGHEST PRICES IN U.S. DOLLARS

NAME OF DRUG (form, strength and quantity)	AVERAGE U.S. PRICE	AVERAGE EEC PRICE	LOWEST PRICE	HIGHEST PRICE
ADALAT* cap, 10mg, 50	19.3	16.2	7.4	29.7
ALDOMET tab, 250mg, 100	25.3	18.0	8.6	32.4
CAPOTEN* tab, 25mg, 50	21.5	27.9	12.5	41.8
CARDIZEM* tab, 60mg, 60	27.5	23.5	12.7	32.5
CECLOR* cap, 250mg, 12	16.3	14.5	8.1	20.7
CLINORIL* tab, 200mg, 100	87.7	62.4	32.7	87.7
DALMANE cap, 30mg, 30	13.0	8.2	2.4	13.8
DIABETA tab, 5mg, 30	11.0	7.5	2.3	15.7
DYAZIDE cap, 25/50mg, 30	11.3	8.4	2.7	16.1
HALCION tab, .25mg, 30	14.6	6.3	3.1	14.6
ISOPTIN SRtab, 240mg, 30	9.1	7.7	3.1	13.2
LASIX* tab, 40mg, 20	3.6	4.5	1.9	9.6
LOPRESSOR* tab, 50mg, 50	34.1	19.8	8.1	36.6
LOZOL tab, 2.5mg, 30	15.4	13.6	5.4	21.6
MICRONASE tab, 5mg, 30	11.6	7.1	2.3	15.7
MODURETIC tab 5/50mg, 30	12.4	9.8	4.3	18.1
NITRODISK(C) patch, 5mg, 30	35.6	41.1	23.8	68.0
RUFEN* tab, 400mg, 30	4.4	7.4	4.0	16.1
SECTRAL cap, 400mg, 30	21.7	20.8	6.4	27.6
SEPTRA* tab, 80/400mg, 20	10.9	7.1	2.8	12.9
TEGRO(E)TOL* tab, 200mg, 50	15.4	10.5	5.8	16.5
VALIUM* tab, 5mg, 25	9.7	3.6	0.9	9.7
VIBRAMI(Y)-CIN(E) cap, 100mg, 10	23.3	15.2	4.3	30.9
XANAX* tab, .25mg, 100	37.5	16.5	6.9	37.5
ZANTAC* tab, 150mg, 20	13.4	29.7	16.4	45.4

Note: Brand name products are reflected in this anaylsis

* For these products, the identical package sizes were not available in every country; therefore, the Belgian Consumers' Association used an economic model to adapt for package size differences.

Appendix E

1988 U.S. DRUG PRICES vs PRICE CONTROLLED AND FREE MARKET PRICES

PRICE INDEX FOR 25 IDENTICAL PRESCRIPTION DRUG PRODUCTS*		
COUNTRY OR GROUP OF COUNTRIES	EUROPEAN ECONOMIC COMMUNITY = 100	PRICE CONTROLLED COUNTRIES = 100
Countries with strict price control system	68	100
EEC average	100	147
Countries with limited price control system	123	180
Countries without price control system	147	216
United States	154	226

* Calculations based on weighted retail prices without VAT (value added tax).

Source: Belgian Consumers' Association, November, 1989.

Appendix F

PRESCRIPTION DRUG CONSUMPTION RATES -- U.S. vs EEC

PER CAPITA EXPENDITURE ON PHARMACEUTICAL PRODUCTS AND PERCENTAGE OF GNP SPENT ON PHARMACEUTICAL PRODUCTS (1988)		
COUNTRY	PER CAPITA EXPENDITURE EEC AVERAGE = 100	TOTAL PHARMACEUTICAL EXPENDITURE AS A % OF GNP
ITALY	98	1.341
FRANCE	124	1.440
GERMANY	150	1.487
UNITED KINGDOM	63	0.884
BELGIUM	88	1.146
NETHERLANDS	63	0.811
SPAIN	56	1.299
EEC AVERAGE	100	1.361
UNITED STATES	152	1.485

Calculations based on and figures from Indicatori Farmaccutici 1989, by Farmindustria, the Italian pharmaceutical manufacturers association.

Appendix G

INTERNATIONAL COMPARISON OF PATIENT COST SHARING

AVERAGE % OF THE PATIENT'S CONTRIBUTION TO THE DRUG RETAIL PRICE (IN A SAMPLE OF 125 PRODUCTS)	
COUNTRY	PERCENTAGE
GERMANY	12
NETHERLANDS	13
LUXEMBOURG	18
GREECE	26
PORTUGAL	32
ITALY	33
SPAIN	35
BELGIUM	42
FRANCE	43
UNITED KINGDOM	52
DENMARK	56
EEC AVERAGE	33

NOTE: In most countries there are many exceptions to the general rules of reimbursement. The disabled, orphans, widows, etc., often obtain drugs without charge. In the U.K., for example, it is estimated that 60% of all National Health Service supplies are free.

Appendix H

Definitions Used in This Staff Report

Buying Group -- an organization representing a group of members (usually hospitals, HMOs and nursing homes) that uses its membership's historical and expected future volume of prescription drug purchases to negotiate with drug manufacturers for lower prices.

Drug Formulary -- a preferred list of drugs chosen based on professional assessment of comparative safety, efficacy and economy.

Formulary Drugs -- the total number of drugs that represent all the entities, dosage forms, strengths and manufacturers or labelers.

Pharmaceutical Equivalents -- drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration.

Pharmacy and Therapeutics ("P&T") Committee -- a group of persons (average of about 10 persons) usually composed of physicians, pharmacists and other health care professionals that acts as the decision-making body regarding drug formulary additions and deletions, and may also design physician and pharmacist education or drug utilization review programs.

Therapeutic Equivalence -- when drug products (whether or not they are pharmaceutically equivalent) can be expected to have the same therapeutic effect when administered to patients under specified conditions.

Therapeutic Substitution -- when a pharmacist may substitute chemically different drugs that can be used for the same indication without permission of the prescriber.

Therapeutic Verification -- when a pharmacist may dispense chemically different drugs that can be used for the same indication after authorization from the prescriber.